

IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF TEXAS
DALLAS DIVISION

UNITED STATES OF AMERICA

v.

NO. 3:15-CR-00496-L

SITESH PATEL

FACTUAL RESUME

In support of Sitesh Patel's plea of guilty to the offenses in Counts 7 and 9 of the Superseding Indictment, Patel, the defendant, Patrick Q. Hall, the defendant's attorney, and the United States of America (the government) stipulate and agree to the following:

ELEMENTS OF THE OFFENSE

To prove the offense alleged in Count 7 of the Superseding Indictment, charging a violation of 18 U.S.C. § 371, that is, Conspiracy to Introduce Misbranded Food into Interstate Commerce with Intent to Defraud and Mislead, the government must prove each of the following elements beyond a reasonable doubt:¹

First: That the defendant and at least one other person made an agreement to commit the crime of introducing misbranded food into interstate commerce with an intent to defraud or mislead, as charged in the Superseding Indictment;

Second: That the defendant knew the unlawful purpose of the agreement and joined in it willfully, that is, with the intent to further the unlawful

¹ Fifth Circuit Pattern Jury Instruction 2.15 (5th Cir. 2015).

purpose; and

Third: That one of the conspirators during the existence of the conspiracy knowingly committed at least one of the overt acts described in the Superseding Indictment, in order to accomplish some object or purpose of the conspiracy.

The elements of Introducing Misbranded Food into Interstate Commerce with an Intent to Defraud and Mislead, a violation of 21 U.S.C. § 331(a) and 21 U.S.C. § 333(a)(2), are as follows:²

First. That the substance was a misbranded food;

Second. That a person caused the introduction of, or delivered for introduction, into interstate commerce misbranded food;

Third. That the food's label was false or misleading in any particular manner; and

Fourth. That a person mislabeled the food with the intent to defraud or mislead.

The elements of Count 9 of the Superseding Indictment, charging a violation of 21 U.S.C. §§ 331(a) and 333(a)(1), that is, Introduction of Misbranded Food Into Interstate Commerce, are as follows:

First. That the substance was a misbranded food;

² 21 U.S.C. § 343(a)(1); 331(a); 321(k), (m); O'Malley, Grenig & Lee, Federal Jury Practice and Instructions, §§ 63:02, 63:03, 63:04 (6th ed.) (modified).

Second. That a person caused the introduction of, or delivered for introduction, into interstate commerce misbranded food;

Third. That the food's label was false or misleading in any particular manner.

STIPULATED FACTS

1. Sitesh Patel admits and agrees that beginning in or around October 2008 and continuing thereafter until at least in or around August 2014, in the Dallas Division of the Northern District of Texas and elsewhere, the defendants USP Labs, and he and others working at USP Labs and S.K. Laboratories, namely Jonathan Doyle, Matthew Hebert, Jacob Geissler, and Cyril Willson, did knowingly and willfully combine, conspire, confederate, and agree to commit an offense against the United States, that is, to introduce misbranded food into interstate commerce with an intent to defraud and mislead, in violation of 21 U.S.C. § 331(a) and 21 U.S.C. § 333(a)(2).

2. The object of the conspiracy was to avoid law enforcement attention and match imported substances with false and misleading product labeling by importing and shipping in interstate commerce a variety of compounds for use and prospective use in dietary supplements with false labeling, rendering the items misbranded under 21 U.S.C. § 343(a)(1).

3. As part of the conspiracy, the co-conspirators identified a variety of potential dietary compounds that they wanted to test as prospective dietary supplement ingredients and use as actual dietary supplement ingredients. The co-conspirators ordered a variety of potential dietary compounds from a Chinese company as prospective

and actual ingredients for use in dietary supplements, and instructed and agreed to have those powders labeled falsely as other food substances. The co-conspirators at USP Labs also sent a variety of potential dietary compounds to their co-conspirators at S. K. Laboratories with the knowledge that the variety of potential dietary compounds were labeled falsely as other substances.

4. Patel was the vice president of S.K. Laboratories, LLC.

5. In November 2008, USP Labs began selling a dietary supplement called Jack3d, which was followed by a dietary supplement called OxyElite Pro in November 2009. Both Jack3d and OxyElite Pro originally contained a substance called 1,3-dimethylamylamine (“DMAA”), which is also known as methylhexaneamine. The DMAA used in Jack3d and OxyElite Pro was a synthetic stimulant manufactured in China. The DMAA USP Labs used was synthetic, meaning that it was made from chemicals in a factory, not obtained from nature.

6. Patel and his co-conspirators came to understand that importing and selling purported natural, plant-based substances would be easier than selling synthetic stimulants—because regulatory agencies would be less likely to question the importation of plant extracts and because retailers would be more willing to sell a product that contained natural ingredients instead of synthetic ones.

7. USP Labs imported numerous substances intended for human consumption, such as DMAA, some, but not all, using false and fraudulent COAs and other false and fraudulent documentation and labeling. For example, in a September 2008 email, Patel instructed Geissler: “Have your supplier create a COA like this.” Some of the false

COAs the USP Labs caused to be created for DMAA shipments stated falsely that the substance in the shipments had been extracted from the geranium plant using a “hydro-alcoholic” extraction method at a 200-to-1 ratio.

8. These statements were false because USP Labs used a synthetic stimulant from a Chinese factory, not a substance extracted from geraniums. In one email exchange from May 2009, Patel told Geissler and Doyle about the DMAA in their products: “lol stuff is completely 100% synthetic [sic].”

9. S.K. Laboratories and Patel contacted USP Labs about using DMAA. USP Labs and Geissler were concerned about importing large amounts of DMAA, which Geissler referred to as a “questionable powder.” Geissler was concerned because, as he told Patel in 2008, the “last thing” he wanted was for USP Labs to be “on the FDA radar.”

10. The DMAA-containing versions of Jack3d and OxyElite Pro became bestselling dietary supplements in the United States, generating hundreds of millions of dollars in sales.

11. In or around September 2010, Patel and S.K. Laboratories received documentation for a shipment of 1,000 kilograms of “Geranium Flower (HG) Powder Extract” that was scheduled to arrive at S.K. Laboratories in California after having been shipped from Texas. Patel and S.K. Laboratories knew that the labeling of the shipment was false because the substance in the shipment was not Geranium Flower Powder Extract, but was instead DMAA, a synthetic stimulant.

12. In early 2012, about a month after the Department of Defense ordered DMAA-containing products pulled from GNC stores on U.S. military bases in order to conduct a safety review of those products, USP Labs provided a misleading answer to a dietary supplement industry publication when asked directly whether its DMAA was naturally sourced.

13. From at least 2008 until at least 2013, USP Labs also frequently imported other potential dietary compounds from China in smaller quantities and under false labeling to determine whether they could be used in new dietary supplements. USP Labs used false labeling so that these test shipments could be mailed from China with no registration required and would not come under scrutiny by regulatory agencies.

14. One of the synthetic test potential compounds that USP Labs imported from China was called aegeline. The first aegeline-containing version of OxyElite Pro, which was called OxyElite “New Formula,” went on sale in November 2012.

15. USP Labs reformulated the DMAA product in summer 2013 to contain aegeline and powder derived from a Chinese herb called cynanchum auriculatum. USP Labs did not perform any test to determine whether cynanchum auriculatum—as an extract, as ground-up roots, or otherwise—was safe or effective.

16. USP Labs agreed that a Chinese supplier would send pulverized roots of cynanchum auriculatum, rather than an ethanol extract. The cynanchum auriculatum powder that USP Labs imported was much cheaper than an actual extract.

17. On or about June 15, 2013, Geissler instructed a Chinese company to have two metric tons of ground cynanchum auriculatum root powder shipped internationally to

S. K. Laboratories in California for inclusion in USP Labs' products, using the false name "cynanchum auriculatum root extract." USP Labs sent false labels listing "cynanchum auriculatum (root) extract" as an ingredient in OxyElite Pro Advanced Formula to retailers and wholesalers, even though that specific root extract was not present in the product. The cynanchum auriculatum-containing product, called OxyElite Pro "Advanced Formula," went on sale in or around August 2013.

18. On or about October 4, 2013, Patel and other defendants shipped and caused the shipment of misbranded OxyElite Pro "Advanced Formula" in interstate commerce. The food was misbranded under the FDCA because of its labeling, which falsely declared cynanchum auriculatum (root) extract as an ingredient even though it was not contained in the product.

19. The defendant agrees that the defendant committed all the essential elements of the offense. This factual resume is not intended to be a complete accounting of all the facts and events related to the offense charged in this case. The limited purpose of this statement of facts is to demonstrate that a factual basis exists to support the defendant's guilty pleas to Counts 7 and Count 9 of the Superseding Indictment.

AGREED TO AND SIGNED this 22 day of February, 2019.

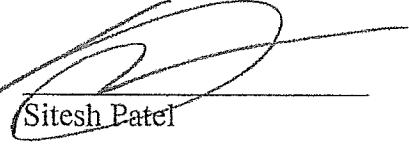
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